

### **Declaration**

The declaration has been objected to for being executed only by Dr. Ronit Rafaeloff-Phail. However, the same declaration was already submitted in executed form by all the other inventors when the reissue application was filed. Applicant believes that 37 C.F.R. §1.75(a)(2) applies to this circumstance. The original oath was defective only with respect to inventor Rafaeloff-Phail. Thus only she needs to sign the supplemental oath.

### **The Rejection of Claims 21, 22, 27, and 28 Under 35 U.S.C. § 251**

Claims 21, 22, 27, and 28 are rejected under 35 U.S.C. § 251 for improperly attempting to recapture subject matter surrendered in the application for the patent upon which the present reissue is based. Applicants respectfully traverse.

The Office Action asserts that claims 21, 22, 27, and 28 improperly attempt to recapture subject matter surrendered during the prosecution of the applications that eventually issued into U.S. Patent 5,840,531 because they recite “a portion.”

Claims 21, 22, 27 and 28 do not run afoul of 35 U.S.C. § 251. Nonetheless, in an effort to expedite prosecution, applicants have amended the claims to cancel recitation of “a portion.” It is respectfully submitted that this obviates the ground of rejection.

### **The Rejection of Claims 1-49 Under 35 U.S.C. § 112, First Paragraph**

Claims 1-49 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

The claims are said to be not enabled for the following reasons:

- Failure to describe hybridization conditions in claim 21;
- Failure to describe the activity of the protein for claims 1 and 29;
- Failure to recite a function of the protein in claims 1 and 21;
- Failure to describe the characteristics of the recited portion in claims 21, 27, and 28.

Each of these alleged failures have been addressed by amendment.

- Claim 21 has been amended to specify that the hybridization conditions are those employed during amplification.
- Claims 1 and 29 have been amended to delete the term activity.
- Claims 1 and 29 have been amended to recite a protein function.
- Claims 21, 27 and 28 have been amended to delete recitation of a portion.

It is respectfully submitted that undue experimentation would not be required to practice the invention based on congruence of the teachings of the specification and the scope of the claims. Withdrawal of the rejection is respectfully requested.

**The Rejection of Claims 1, 6, and 21 under 35 U.S.C. § 112, First Paragraph**

Claims 1, 6, and 21 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

Claim 1 was allegedly indefinite because the type of “activity” was not specified. This term has been deleted and, in addition, a specific activity has been recited in the claim.

Claim 6 was allegedly indefinite because of the virgule. This punctuation has been replaced to clarify the meaning of the term.

Claim 21 was allegedly indefinite because the phrase “consisting of nucleotides 12 to 456 of SEQ ID NO: 4” could have been construed as modifying either a portion or INGAP itself. The term “a portion of the human INGAP” has been deleted to clarify the possibly confusing syntax.

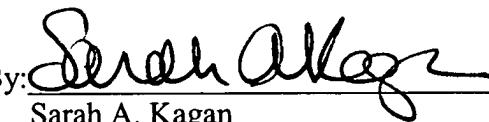
It is respectfully submitted that all indefiniteness raised has been addressed by the amendments and that the claims are now clear.

**Provisional Double Patenting Rejection of Claims 1-49**

Claims 1-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Reissue Application No. 09/717,095 as well as non-provisionally rejected over the underlying Patent, U.S. 5,840,531. Applicants respectfully traverse.

Applicants do not believe that the claims of the pending application and the cited application and patent are patentably indistinct. Nonetheless, to advance prosecution, applicants submit a terminal disclaimer.

Respectfully submitted,

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Dated: October 30, 2002

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Claim Amendments

Please amend claims 1, 6, 21, 27, and 29 as follows.

1. (Amended) A recombinant construct for expression of a protein which stimulates islet cell neogenesis [Islet Neogenesis Associated Protein or INGAP activity] comprising:

*C1*  
a first nucleotide sequence encoding amino acid[s] residues 27 to 175 as shown in SEQ ID NO: 6 operably linked to a transcriptional initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide is not present immediately 5' of said first nucleotide sequence.

*C2*  
6. (Amended) The construct of claim 1 wherein the transcriptional initiation site is the lac promoter [/] and operator.

*C3*  
21. (Amended) A pair of oligonucleotide primers for amplifying a coding sequence consisting of nucleotides 12 to 456 of SEQ ID NO: 4, wherein each of said oligonucleotide primers hybridizes to an opposite strand of a double-stranded INGAP template under conditions sufficient for amplifying, wherein a first of said oligonucleotide primers hybridizes to the 5' end of the coding sequence for mature human INGAP and the second of said oligonucleotide primers hybridizes to the 3' end of the nucleotide sequence encoding mature human INGAP under conditions sufficient for amplifying nucleotides 12 to 456 of SEQ ID NO: 4.

*C4*  
27. (Amended) The method of claim 23 wherein the coding sequence for mature human INGAP is obtained by amplification of a coding sequence consisting of nucleotides 12 to 456 of SEQ ID NO: 4.

29. (Amended) A recombinant construct for expression of a protein which stimulates islet cell neogenesis, comprising:

*CS*  
a first nucleotide sequence encoding mature human INGAP consisting of nucleotides 12 to 456 of SEQ ID NO: 4, said first nucleotide sequence being operably linked to a transcriptional initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide according to SEQ ID NO: 5 is not present immediately 5' of said first nucleotide sequence.